Pharma, national security and tariffs: Where do we go from here?

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After the tariff frenzy of the first quarter of this year, we've sailed into the doldrums. Not that the tariffs have gone away, or the threat of new ones has subsided, or there is a solid prospect of a non-tariff settlement discernible in the horizon, but that the *pace* of movement, of change, and of threats has slowed down. We can take a sigh of relief for this minor, if passing, blessing.

And take stock.

The last sector targeted by tariffs before relative calm descended upon us was the pharmaceutical industry. On April 1, 2025, the U.S. Department of Commerce announced the launch of an investigation under Section 232 of the *Trade Expansion Act of 1962*, as amended, to assess whether imports of pharmaceuticals and pharmaceutical ingredients threaten national security. Shortly thereafter, on May 12, 2025, President Trump signed an executive order ostensibly aimed at reducing drug prices for American consumers.

In this insight, we examine how these two initiatives intersect. Should we expect greater security of access and affordability for pharmaceutical products? How would the U.S. proceed to *reduce* drug costs for American consumers even as tariff measures increase prices of both inputs and imported products?

And what can the rest of us do? We conclude by discussing Canada's options to combat, or at least mitigate, the volatility in drug prices that may come as a result of these U.S. policies.

What is Section 232? A refresher

Historical use

Section 232 gives the President broad authority to investigate whether imports threaten U.S. national security.[1]

Historically, Section 232 investigations were used infrequently. They were primarily focused on imports of strategic goods such as oil, uranium, and specialty metals, particularly in the context of national defence. The provision saw a significant resurgence during President Trump's first term, most notably through the 2018 tariffs on steel and aluminum. This marked a shift toward using Section 232 as a broader instrument of economic and industrial policy, extending its application beyond traditional national security threats. Between 2017 and 2025, a total of 17 inquiries have been initiated, including those that remain ongoing. This figure is approximately equal to the number of inquiries conducted during the entire period from 1970 to 2016. As an example, in 2025 alone, President Trump has initiated seven new Section 232 investigations, including the one into pharmaceutical and pharmaceutical ingredients.

How do they work?

Section 232 provides that an investigation may be initiated by the Secretary of Commerce on their own initiative, at the request of the head of another federal department or agency, or in response to a petition from an interested party.

An investigation initiated under Section 232 must consider the following factors:

- **Domestic production for national defence**
  - The capacity of U.S. industries to meet projected national defence requirements;
- **Domestic industry capability**
  - The capacity of domestic industries to meet national defence needs;
- **Availability of critical resources**
  - The availability of human resources, products, raw materials, production equipment and facilities, among other related considerations;
- **Requirements for industrial growth:**
  - The growth requirements of domestic industries and critical supplies and services to meet national defense requirements;
- **Nature and circumstances of imports:**
  - The quantity, availability, character and use of imports and how they affect U.S. industry;
- **Economic welfare and national security :**
  - The close relation of the Nation's economic welfare to national security;
- **Impact of foreign competition:**
  - The impact of foreign competition on the economic welfare of U.S. industries;
- and other factors.

Investigation reports must be submitted to the President no later than 270 days from the commencement of the investigation. Each report must set forth a determination as to whether the subject imports threaten to impair national security, accompanied by the investigatory body's findings and any pertinent recommendations. Once the President receives the report, he has 90 days to decide whether or not he concurs with the findings and recommendations. The President may implement the recommendations suggested in the report or take other actions or decide to take no action. The President

has broad discretion to respond, including imposing tariffs, setting import quotas, or taking other necessary measures to address national security concerns.

With the mechanics of Section 232 in view, it is worth turning to the underlying question driving the 2025 pharmaceutical investigation: where do U.S. drugs–and the ingredients used to make them–actually come from? Understanding the structure and geography of the pharmaceutical supply chain is essential to evaluating whether national security concerns are justified.

U.S. pharma: the origin story

The U.S. pharmaceutical supply chain is heavily globalized, with a significant portion of both active pharmaceutical ingredients (APIs) and finished drug products sourced from overseas. More than half of the APIs used in prescription drugs sold in the United States–both generic and brand-name–are sourced from India and the European Union (EU). For generic drugs specifically, India, China and the EU supply over 60 per cent of all APIs, while the United States produces just 12 per cent of its own APIs. When it comes to brand-name drugs, the same three regions account for roughly half of all APIs, compared to 15 per cent being manufactured in the U.S.

Some 90 per cent of all prescriptions dispensed in the United States are for generic medication. However, despite their high volume, generic drugs constitute only about 13 per cent of total pharmaceutical *expenditures*, whereas brand-name drugs constitute the bulk of total pharmaceutical spending. In practical terms, this means that over half of all prescriptions relied on by Americans are produced using APIs sourced oversees.

The deep integration of the United States into the global pharmaceutical supply chain has no doubt delivered significant cost savings and efficiency for American consumers over the years; it has also made it reliant on foreign drug manufacturing.

So what about the presidential executive order aimed at reducing the cost of drugs.

Executive Order: “Zap, you’re cheaper”

On May 12, 2025, President Trump signed an Executive Order aimed at reducing prescription drug costs in the United States by aligning them with the lowest prices paid by other developed nations–a policy known as "most-favoured-nation" (MFN) pricing. In typical fashion, a day before signing the Executive Order, President Trump posted on his social media platform that drug prices would be reduced “almost immediately, by 30 per cent to 80 per cent”.[2]

The Executive Order mandates that within 30 days, the Department of Health and Human Services (HHS) is to engage with pharmaceutical manufacturers to reach “MFN” pricing targets. Should these negotiations fail to yield "significant progress," the administration plans to initiate formal rulemaking to enforce “MFN” pricing standards. This approach mirrors a similar initiative from President Trump's first term, which faced legal challenges and was ultimately blocked by a federal court. This initiative has the

potential to create significant reductions in U.S. drug prices; but even the Executive Order itself makes plain that any savings will not be achieved quickly.

Americans have historically paid higher drug prices than their foreign counterparts. An international study of prescription drug pricing conducted by the RAND institute found that, on average, prices in the United States were nearly three times higher than those in other high-income countries. This disparity was particularly pronounced for brand-name drugs, which were priced at approximately four times the level found elsewhere, whereas U.S. generic drugs were, on average, about one-third less expensive than their international counterparts.

Following the Executive Order, the pharmaceutical industry voiced strong opposition, asserting that policies threatening their profit margins may undermine incentives for further investment in pharmaceutical research and development. This is a standard position for the industry. And it is not without basis. It is true that some studies have questioned a causal link between higher drug prices and increased R&D spending, suggesting that the relationship may not be as direct or robust as industry stakeholders claim.[3] At the same time, other studies have found that a ten percent growth in real drug prices leads to a near six percent increase in the growth of R&D spending. The jury is still out; neither position should be dismissed out of hand.

The Executive Order also directs the Secretary of Commerce and the United States Trade Representative to ensure that foreign countries are not acting in a way that may "impair United States national security" and force "American patients to pay for a disproportionate amount of global pharmaceutical research and development." The suggestion is that, by implementing pharmaceutical price controls and other price suppression policies, other countries are passing the cost of drug research and development onto the United States. The underlying threat appears to be that the United States is prepared to implement unilateral trade measures, such as tariffs, against such countries unless they drop or alter such policies.

The bottom line

A Section 232 investigation and the MFN Executive Order operate with different policy objectives–national security versus lower costs for U.S. patients–but they are not inherently contradictory, and some aspects of these policies may function in a complementary manner.

In theory, tariffs and other trade measures may be used as strategic negotiating tools to achieve the objectives of the MFN Executive Order by pressuring U.S. trading partners to remove price controls on pharmaceuticals. If the U.S. Administration's theory about the effect of drug price suppression or depression in foreign markets holds true, this may cause the reduction of drug prices in the U.S.

As well, in theory, the same trade measures could pressure manufacturers of critical pharmaceuticals and pharmaceutical ingredients to return production to the United States, insulating American patients from the potentially catastrophic effects of broken supply chain links caused by war or other global calamities, thereby achieving the usual policy objectives stemming from a Section 232 investigation.

In theory.

We can identify at least three challenges here.

First, it is not a given that increased prices in *foreign* markets will cause pharmaceutical manufacturers to decrease prices in the U.S. This assumed that the increased prices would not be subject to industrial policy and taxation considerations in other jurisdictions that would try to recapture at least *some* of the cost increases. We could conceivably end up in a situation that an increase in global drug prices gives rise to domestic U.S. prices increases.

The second challenge is public choice theory and the stickiness of protectionist measures. Domestic interests used to the protection – and higher prices – offered by a tariff regime will not give up that protection easily. There is always a good argument to be made why tariffs should continue even after concessions are made by trading partners. What then?

Third, reshoring does not always – if ever – result in lower domestic prices. (If lower, competitive prices could be achieved, arguably, the sector would not have off-shored in the first place.) Supply chain reshoring, for any product, is rarely immediate or efficient; it is an inherently protracted and capital-intensive endeavour that will inevitably complicate the execution of any restrictive trade measures.

The difficulties in reworking supply chains are amplified in the pharmaceutical industry, which depends on a web of carefully woven links navigating the onerous, and inconsistent, jurisdiction-to-jurisdiction regulations imposed on the pharmaceutical sector.

This would suggest that trade restrictions imposed under Section 232 is likely to precipitate supply constraints and elevate production costs. Without interim solutions such as strategic stockpiling or diversified sourcing, Section 232 tariffs will rather undermine than complement the affordability goals of the MFN Executive Order.

What this means for Canadians

Canadian exports are a small part of the U.S. drug supply. We will not be immune to the direct and indirect effects of pricing changes, supply chain rerouting, or tariffs (both targeted and blanket).

The MFN Executive Order framework effectively seeks to have American patients pay no higher price for drugs than any other patient in the world. Pharmaceutical firms might react to pressures from the U.S. Administration by withholding new drugs from the Canadian market, raising prices in Canada to keep U.S. reference prices high, or reducing supply or delaying launches to avoid creating low price comparators for the U.S.'s new MFN pricing policies.

Faced with the threat of such harms, Canada could accelerate its own pharmaceutical manufacturing capabilities–a trend seen during COVID-19–as a means to secure domestic sources of pharmaceuticals.

The Section 232 investigation and the MFN executive order pursue distinct policy goals: safeguarding domestic supply chains and reducing drug prices for American patients. In some respects, the two policies may be complementary, as trade measures can support both objectives. However, each faces practical challenges in achieving its stated aims. The policies may also conflict. Returning pharmaceutical manufacturing to the U.S. and increasing supply chain complexity is likely to raise drug costs. Canada has some tools to address the direct and indirect effects of Section 232 orders and the MFN executive order, but Canadians should nonetheless prepare for volatility in the price of their medications.

Planning for the impact of these measures requires strategic, informed action. Our international trade lawyers can help you assess risk, manage compliance and protect your business interests. Contact our team today to discuss how these evolving policies may affect your supply chains, pricing strategies and cross-border operations.

Footnotes

[1] 19 U.S.C. § 1862 (*Trade Expansion Act of 1962*, Section 232).

[2] President Trump, Truth Social post, May 11, 2025.

[3] Angelis et al., High drug prices are not justified by industry's spending on research and *development, BMJ, 2023* and Wouters et al., *Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018*, JAMA Network, 2022.

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